

CLAIMS :

1. A screening device for interpreting the lines of an immunoassay test having discretely located test zones and a control zone interposed between background zones, said device comprising:
- a light source for illuminating an immunoassay test;
 - an array of photosensitive detectors for detecting the intensity of light which is reflected from said test zones, control zone and background zones of said immunoassay test;
 - a digitiser, coupled to the output of said array of photosensitive detectors, for representing said intensity of detected light by a data array;
 - a store for storing preset data;
 - first data processor, coupled to said store and to the output of said digitiser, for segmenting said data array according to said preset data into control data, background data and test data;
 - a second data processor, coupled to said first data processor, for determining whether said test data exhibits a statistically significant result; and
 - an output, coupled to the output of said second data processor, for outputting the results from said second data processor.
2. A screening device according to claim 1, wherein said second data processor compares said control data, background data and test data to determine whether said test data exhibits a statistically significant result compared to said control data and background data.
3. A screening device according to claim 1, wherein said second data processor is provided with null data, said null data being representative of the intensity of light

reflected from said background areas between said lines, said second data processor comparing said test data and said null data to determine whether said test data exhibits a statistically significant result.

5 4. A screening device according to claim 1, wherein a timer is provided for delaying said illumination of said immunoassay test until said immunoassay test has been completed.

10 5. A screening device according to claim 1, wherein said first and second data processors are provided by a central processor unit.

15 6. A screening device according to claim 5, wherein serial and parallel ports are provided from said central processor unit to allow said screening device to be controlled from an external processor or to allow said screening device to download the results of said comparison of the control data, background data and test data.

20 7. A screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a charge coupled device, associated video digitiser and video data interface.

25 8. A screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a CMOS imaging sensor, associated driver and video buffer.

9. A screening device according to claim 1, wherein said output is a display.

10. A screening device according to claim 1, wherein said immunoassay test is conducted on a saliva sample.

11. A screening device according to claim 1, wherein said immunoassay test is performed in a disposable test cartridge.

12. A screening device according to claim 1, wherein said
5 first data processor includes a filter for filtering said data array prior to determining whether said test zones exhibit statistically significant results.

13. A screening device according to claim 1, wherein
10 a timer, coupled to said first processor produces a delay before said first processor segments the data.

14. A method of screening an immunoassay test having
discretely located test zones and a control zone interposed
between background zones where the result of said test is
indicated by the amount of a marker deposited in said test
15 zones compared to said background and control zones, said method comprising the steps of:

illuminating said immunoassay test;
detecting the intensity of light reflected from said
control zone, test zones and interposed background zones of
20 said immunoassay test and converting said detected intensity to a data array;

segmenting said data array into first, second and
third pluralities of data, said first plurality of data
corresponding to said control zone, said second plurality of
25 data corresponding to said test zones, said third plurality of data corresponding to said background zones;

processing said second plurality of data to determine
whether said second plurality of data shows a substance
level above a threshold; and

30 outputting the results of said processing.

15. A method of screening an immunoassay test according
to claim 14, wherein said threshold is set by reference to
said first and third pluralities of data.

16. A method of screening an immunoassay test according to claim 14, wherein said immunoassay test is conducted on a saliva sample.

17. A method of screening an immunoassay test according to claim 14, wherein said outputted results are displayed on a liquid crystal device.

18. A screening device for interpreting the results of an agglutination test, said test having areas of coagulation and background areas, said device comprising:

10 a light source for illuminating said test;

an array of photosensitive detectors for detecting the intensity of light from said light source which is reflected from said areas of coagulation and background areas of said agglutination test;

15 a digitiser, coupled to the output of said array of photosensitive detectors, for representing said intensity of the detected light by a data array;

20 a threshold processor, coupled to the output of said digitiser, for thresholding said digitised data to distinguish between background areas and areas of coagulation;

25 a first data processor, coupled to said threshold processor, for identifying from said thresholded data areas of coagulation and estimating the size of said areas of coagulation;

a second data processor, coupled to the output of said first data processor, for determining whether said areas of coagulation exhibit a statistically significant result; and

30 an output, coupled to said second data processor, for outputting the results from said second data processor.

19. A screening device according to claim 18, wherein

a noise reduction processor is coupled between the output of said digitiser and said first data processor for performing noise reduction on said digitised data.

20. A method of screening an agglutination test, said
5 test having areas of coagulation and background areas, said method comprising the steps of:

illuminating said test;
detecting the intensity of light which is reflected
from said areas of coagulation and background areas of said
10 agglutination test;
representing the intensity of said detected light in
a data array;
thresholding said data array to distinguish between
background areas and areas of coagulation;
15 identifying areas of coagulation and estimating the
number of said areas of coagulation;
determining whether said areas of coagulation exhibit
a statistically significant result; and
outputting said results.

- 20 21. A method according to claim 20, wherein noise
reduction of said digitised data is performed prior to
thresholding said digitised data.

22. A swab for taking a sample of bodily fluid and
transferring said sample to a test strip, said swab
25 comprising:

a collection pad, a tube, a run fluid chamber and an
elongate spike;
said tube having a bore running axially along its
length and having open upper and lower ends, said lower end
30 of said tube being disposed axially adjacent to and in
communication with said collection pad;

said run fluid chamber being located in said bore of
said tube; and

said elongate spike being moveable in said bore of said tube from a sampling position to a sample transferring position, said elongate spike being axially remote from said run fluid chamber in said sampling position and piercingly contacting said run fluid chamber in said sample transferring position.

23. A swab according to claim 22, wherein a detector is provided for detecting that an adequate sample of bodily fluid has been collected.

24. A swab according to claim 23, wherein said detector is located in said tube and comprises a dye release pad and a dye receptor pad, said dye release pad being positioned in closer axial proximity to said collection pad than said dye receptor pad, and said tube being substantially transparent in the vicinity of said dye receptor pad.

25. A swab according to claim 24, wherein a filter pad is located axially between said collection pad and said dye release pad.

26. A swab according to claim 22, wherein an outer tube is provided, said outer tube being open at the lower end thereof and housing said upper end of said tube; said elongate spike being held captive between said tube and said outer tube, said outer tube being moveable relative to said tube whereby movement of said outer tube relative to said tube causes said elongate spike to move from said sampling position to said sample transferring position.

27. A swab for taking a sample of bodily fluid and transferring said sample to a test strip, said swab comprising:

a collection pad, a main tube, a run detector and a capillary tube;

said main tube having an axial bore and being open at the lower end thereof, said lower end of said tube being disposed axially adjacent to and in communication with said collection pad; and

5 said capillary tube being open at the upper and lower ends thereof, said open lower end of said capillary tube being in communication with said collection pad and said run detector being located in said capillary tube, the distance between said run detector and said collection pad being such
10 that said run detector detects when an adequate sample of bodily fluid has been collected.

28. A swab according to claim 27, wherein the wall of said main tube defines a port, said open lower end of said capillary tube being connected to said port and
15 communicating with said main tube.

29. A swab according to claim 28, wherein said run detector comprises a dye release pad and a dye receptor pad, said dye release pad being positioned in closer proximity to said lower end of said capillary tube than said dye receptor pad.

20 30. A swab according to claim 27, wherein a pierceable run fluid chamber is located in said main tube.